

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of: SMOLA, et al.

Confirmation No.: 2943

Application No.: 10/596,159

Group Art Unit: 1611

Filing Date: June 1, 2006

Examiner: PURDY, Kyle

For: NUTRITIONAL COMPOSITION
FOR WOUND HEALING

Attorney Docket No.: 7274-US-PCT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S REPLY BRIEF

Sir:

I. INTRODUCTION

Appellant submit Appellant's Reply Brief in response to the Examiner's Answer dated October 16, 2009 pursuant to 37 C.F.R. § 41.41(a). Appellant respectfully submits that the Examiner's Answer has failed to remedy the deficiencies with respect to the Final Office Action dated March 4, 2009 as noted in Appellant's Appeal Brief filed on May 22, 2009, for at least the reasons set forth below. Accordingly, Appellant respectfully requests that the rejections of pending Claims 1-5 be reversed.

II. THE REJECTION OF CLAIMS 1-5 UNDER 35 U.S.C. § 103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS NOT ESTABLISHED A PRIMA FACIE CASE OF OBVIOUSNESS WITH RESPECT TO THE CITED REFERENCES

Appellant respectfully requests that the Board reverse the rejections of Claims 1-5 under 35 U.S.C. §103(a) because the Examiner has still failed to establish a *prima facie* case of obviousness with respect to the cited references. Appellant respectfully submits that the cited references fail to disclose or suggest each and every element of the present claims and that the skilled artisan would have no reason to combine *Gray* and *McEwen* to arrive at the present claims.

A. The Presently Claimed Compositions

Independent Claim 1 recites, in part, a nutritional composition for promoting wound healing comprising not more than 1.8% of the total calories of the composition as arginine and at least 3% of the total calories of the composition being proline. In recent years, much attention has focused on the role of arginine in wound healing. An adequate supply of arginine is clearly relevant to the wound healing process. However, arginine is also a precursor for the formulation of nitric oxide which acts as a vasodilator and enhances growth hormone secretion. It is not desirable for critically ill individuals to be exposed to high amounts of nitric oxide and yet this will inevitably happen if such individuals receive nutritional supplements containing high levels of arginine.

Further, it is quite likely that a high proportion of elderly, bedridden or critically ill patients at risk of developing pressure sores will also suffer from conditions for which high levels of nitric oxide are contra-indicated. See, specification, page 2, lines 8-17. Accordingly, the present invention is supplemented with proline in a quantity sufficient to facilitate collagen synthesis and small amounts of arginine that account for no more than 1.8% of the total calories of the compositions. See, specification, page 3, lines 9-32. In contrast, Appellant respectfully submits that the skilled artisan would have no reason to combine the cited references to arrive at the present claims because *Gray* teaches away from *McEwen* and from the present claims.

B. *Gray* Teaches Away From Both *McEwen* and the Presently Claimed Compositions

1. *Gray* teaches away from *McEwen*

- a. *Gray* teaches away from *McEwen* with respect to the amount of arginine required

In the Examiner's Answer, the Examiner expressly states that "*Gray* teaches using arginine in their composition in an amount of at least 3% of the total calories of the composition, which is above that which Appellant is claiming." See, Examiner's Answer, page 5, lines 7-9. However, the Examiner also asserts that "*McEwen* . . . teaches that arginine can accelerate wound healing when present in a composition in an amount of about 1% of the total caloric content" and that "any ordinary person would have had a reasonable expectation for arriving at a composition capable of accelerating wound healing by using an intermediate value between those deemed useful by the prior art, e.g. 1% and 3%." See, Examiner's Answer, page 6, lines 2-6. The Examiner further alleges that such disclosures, "in effect . . . provide[s] a useful working range in which a person could provide arginine to a subject to accelerate wound healing." See, Examiner's Answer, page 6, lines 6-8. As support for this assertion, the Examiner cites MPEP 2144.05, which allegedly teaches that a range can be disclosed in multiple prior art references instead of a single prior art reference and that "where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a prima facie case of obviousness exists." See, Examiner's Answer, page 6, lines 10-14. Appellant respectfully disagrees.

For example, Appellant submits that there exists no established "overlapping range" of an amount of arginine disclosed by the cited references. For example, *Gray* discloses an amount of arginine that is "at least 3%." See, *Gray*, column 6, lines 58-62. This means that the amount of arginine disclosed by *Gray* cannot be lower than 3%. Indeed, the Examples of *Gray* use amounts of arginine that are around 12-13% arginine. See, *Gray*, Examples.

In contrast, *McEwen* discloses that arginine may comprise about 1% of the total calories of the product. See, *McEwen*, column 9, lines 3-5. *McEwen* also discloses that the arginine may be present in an amount of about 5%. See, *McEwen*, column 7, lines 32-35. Accordingly, the only possible overlap of arginine ranges between *Gray* and *McEwen* is above 3%, which is well above the presently claimed amount of arginine. Accordingly, Appellant respectfully disagrees

that there exists an “overlapping range” of an arginine amount and that the “overlapping range” renders the present claims *prima facie* obvious.

The Examiner also asserts that “since *Gray* suggests a mixture of arginine and proline[,] if a final composition implements a mixture of proline and arginine, the relative amounts of each would correspondingly decrease” since the “teaching of at least 3% arginine refers to the use of arginine alone prior to mixing with proline.” See, Examiner’s Answer, page 6, lines 18-21. Appellant respectfully submits that this is an unfounded assumption on the part of the Examiner. For example, the use of the phrase “at least” does not require a specific amount of arginine such that the specific amount of arginine must decrease or increase depending on the amount of proline introduced in the composition. Further, *Gray* also does not specify that the remaining 97% of the composition should remain at fixed proportions, while the amount of proline may vary. As such, the amounts of the other components of the composition can combine to form an indefinite number of combinations of amounts of ingredients. Accordingly, Appellant submits that the Examiner’s conclusion that the amount of arginine must increase or decrease with the introduction of proline is ill-founded.

Appellant respectfully submits that *Gray* teaches away from combination with *McEwen* with respect to the amount of arginine required in the composition. For example, *Gray* explicitly discloses “at least 3% of the total calories as arginine.” *Gray* further discloses that “[e]nhanced wound healing with arginine is believed to be provided at quantities greater than 3% of the total calories.” See, *Gray*, column 6, lines 58-62 (emphasis added). Accordingly, *Gray* explicitly teaches that, at the very least, 3% of the total calories of the composition are from arginine. This is in direct contrast to *McEwen*, which discloses compositions comprising about 1% arginine with respect to the total calories of the nutritional products. Specifically, *McEwen* discloses that “[d]esirably, the arginine will comprise about 1% of the total calories of the nutritional products.” See, *McEwen*, column 9, lines 3-5. Indeed, *McEwen* explicitly teaches that an amount of arginine may be used in a composition that is much lower in the arginine content required by *Gray*.

- b. *Gray* teaches away from *McEwen* with respect to the amount of proline required

In the Examiner's Answer, the Examiner asserts that "*McEwen* does not need to teach proline since *Gray* motivates one to [use same]." The Examiner further asserts that the "prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed." See, Examiner's Answer, page 8, lines 17-19. Appellant respectfully disagrees.

The Examiner expressly states that "it is clear that a proline and arginine combination will be effective and will not have a deleterious effect on wound healing based on *Gray*'s teachings." See, Examiner's Answer, page 9, lines 2-4. However, the Examiner admits that column 6 of *Gray* discloses proline in an amount of about 1.5% and asserts that *Gray* also teaches a composition containing "at least 2.0%" proline. See, Final Office Action, page 2, lines 19-22. As such, the Examiner cites *Gray*, at least in part, for the disclosure of a minimum amount of proline in the disclosed compositions. This is in direct contrast to *McEwen*, which fails to disclose or even suggest the use of proline. Instead, *McEwen* is entirely directed toward an elemental liquid nutritional product useful for providing nutrition to a patient having a malabsorption condition by enterally feeding to the patient a nutritional composition having a specific caloric density. See, *McEwen*, Abstract. *McEwen* fails to even disclose the use of proline in a nutritional composition at any place in the disclosure, let alone a minimum amount of proline, including, for example, at least 2% of the total calories of the composition being proline.

As such, because the cited references disclose completely different amounts of arginine and proline, the skilled artisan would have no reason to combine *Gray* with *McEwen* to arrive at the present claims. In fact, what the Examiner has done here is to apply hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses. Instead, the skilled artisan must have a reason to combine the cited references to arrive at the present claims. Appellant respectfully submits that such a reason is not present in the instant case.

Appellant also respectfully submits that each reference must be considered as a whole and those portions teaching against or away from each other and/or the claimed invention must be considered. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve Inc.*, 796 F.2d 443 (Fed. Cir. 1986). “A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant.” *Monarch Knitting Machinery Corp. v. Fukuhara Industrial Trading Co., Ltd.*, 139 F.3d 1009 (Fed. Cir. 1998), quoting, *In re Gurley*, 27 F.3d 551 (Fed. Cir. 1994).

2. Gray teaches away from the present claims

Appellant respectfully submits that in its attempt to arrive at the present claims by combining the cited references, the Examiner has ignored significant portions of *Gray* that teach away from the presently claimed subject matter. In the Examiner’s Answer, the Examiner does not refute this argument.

The formulations of *Gray* are explicitly disclosed as including “at least 3% of the total calories as arginine.” *Gray* further discloses that “[e]nhanced wound healing with arginine is believed to be provided at quantities greater than 3% of the total calories.” See, *Gray*, col. 6, lines 58-62 (emphasis added). This is in direct contrast to the present claims, which require, in part, a nutritional composition for promoting wound healing comprising not more than 1.8% of the total calories of the composition as arginine.

Arginine is a precursor for the formulation of nitric oxide which acts as a vasodilator and enhances growth hormone secretion. It is not desirable for critically ill individuals to be exposed to high amounts of nitric oxide and yet this will inevitably happen if such individuals receive nutritional supplements containing high levels of arginine. It is also quite likely that a high proportion of elderly, bedridden or critically ill patients at risk of developing pressure sores will also suffer from conditions for which high levels of nitric oxide are contra-indicated. See, specification, page 2, lines 8-17. Accordingly, the presently claimed composition is supplemented with small amounts of arginine that account for not more than 1.8% of the total calories of the compositions. See, specification, page 3, lines 9-32. *Gray* specifically teaches away from the claimed subject matter when *Gray* teaches that the composition contains “at least 3% of the total calories as arginine.” See, *Gray*, column 6, lines 58-62 (emphasis added).

Thus, Appellant respectfully submits that this disclosure of *Gray* would actually lead the skilled artisan in a direction divergent from the path that was taken by Appellant in the present disclosure. *In re Haruna*, 249 F.3d 1327 (Fed. Cir. 2001). See, also, MPEP 1504.03. In other words, the explicit teaching of *Gray* that the composition contains “at least 3% of the total calories as arginine” would direct the skilled artisan to include more arginine than is required or taught by the present claims, which include arginine in amounts that are not more than 1.8% of the total calories of the compositions. As a result, one having ordinary skill in the art would have no reason to combine the cited references to arrive at the present claims.

For the reasons discussed above, Appellant respectfully submits that Claims 1-5 are novel, nonobvious and distinguishable from the cited reference.

Accordingly, Appellant respectfully requests that the rejection of Claims 1-5 under 35 U.S.C. §103(a) be withdrawn.

III. CONCLUSION

For the foregoing reasons, Appellant respectfully submits that the Examiner’s Answer does not remedy the deficiencies noted in Appellant’s Appeal Brief with respect to the Final Office Action. Therefore, Appellant respectfully requests that the Board of Appeals reverse the obviousness rejections with respect to Claims 1-5.

No fee is due in connection with this Reply Brief. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 50-4498 in the name of Nestle Nutrition.

Respectfully submitted,

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